IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG

ASTRAZENECA AB and ASTRAZENECA PHARMACEUTICALS LP, Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and KINDEVA DRUG DELIVERY L.P., Defendants.	Civil Action No.: 1:22:cv-00035-GMG

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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I. INTRODUCTION

In the Complaint, AstraZeneca seeks relief under two separate statutory schemes: the Hatch-Waxman Act which is a specialized Act that encourages early litigation between brand and generic pharmaceutical companies and has remedies available only to it (Count 1), and the Declaratory Judgment Act, alleging imminent infringement under the Patent Act (Count 2). Defendants, Mylan Pharmaceuticals Inc. ("Mylan") and Kindeva Drug Delivery L.P. ("Kindeva") (collectively, "Defendants"), respectfully move this Court to dismiss Count 1 of Plaintiffs' Complaint for failure to state a claim under Rule 12(b)(6) because this case is not a Hatch-Waxman case.[1]

The Hatch Waxman Act allows brand pharmaceutical companies to assert certain patents covering their products while the generic companies are seeking FDA approval of their versions, instead of having to wait until the generic has launched or is about to launch. This allows the companies to resolve patent disputes sooner and, where appropriate, "speed the introduction of low-cost generic drugs to the market." *Celgene Corp. v. Mylan Pharms. Inc.*, 17 F.4th 1111, 1117 (Fed. Cir. 2021) (quoting *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012)). And while this case does involve Mylan's generic version of AstraZeneca's Symbicort® products, it comes years *after* Defendants' filed their Abbreviated New Drug Application ("ANDA") with the FDA and *after* that ANDA was approved by the FDA. The Hatch-Waxman Act does not apply in this situation.

The FDA's approval of Mylan's ANDA dooms AstraZeneca's quest for relief under the Hatch-Waxman Act, as that is only available to suits properly brought under it. The patent at issue in this case, U.S. Patent No. 11,311,558 ("'558 patent") was not even in existence at any time

[1] Defendants will separately file an Answer and Counterclaims to Count 2 of the Complaint, and are not moving to dismiss Count 2 here.

Mylan's ANDA was pending FDA approval. Therefore, AstraZeneca's plea for relief for remedies that are only available under the Hatch-Waxman Act before the ANDA has been approved, are baseless here and should therefore be dismissed under Federal Rule of Civil Procedure 12(b)(6). *See* Compl. ¶¶ 53–60, ECF No. 1 (pleading infringement under 35 U.S.C. § 271(a)); *id*. at Prayer for Relief at A, C-F (requesting Relief under 35 U.S.C. § 271(e)(4)).

II. BACKGROUND

A. THE PATENT-IN-SUIT

The '558 patent, titled "Composition for Inhalation," is directed to a formulation containing active ingredients budesonide and formoterol, inactive ingredients PVP and PEG, and propellant HFA 227, for use in a pressurized metered dose inhaler ("pMDI") to treat inflammatory respiratory conditions such as asthma and COPD. *See* ECF No. 1-2 ('558 patent) at 1:5-37; *see also* Compl. ¶ 11. The '558 patent issued on April 26, 2022, and the named inventors on the face of the patent are Nayna Govind and Maria Marlow, and it is assigned to AstraZeneca AB. ECF No 1-2. The '558 patent contains one independent claim, claim 1, and ten claims that depend from claim 1 and are directed generally to a formulation and certain respiratory disorder treatments. Claim 1 states:

> 1. A pharmaceutical composition comprising formoterol, budesonide or an epimer thereof, 1,1,1-2,3,3,3-heptafluoropropane (HFA 227), about 0.0005 to about 0.05% w/w polyvinyl pyrrolidone (PVP) K25, and about 0.05 to about 0.35% w/w polyethylene glycol (PEG) 1000 (PEG having an average molecular weight of 1000 Daltons).

Id. The '558 patent will expire in a little under eight months – on January 29, 2023.

B. THE HATCH-WAXMAN STATUTORY FRAMEWORK

Under the Hatch-Waxman Act framework, generic-drug sponsors can submit an Abbreviated New Drug Application ("ANDA") for a product bioequivalent to a reference drug. *Celgene*, 17 F.4th at 1117. Brand-drug sponsors are required to provide the FDA with the patents they assert cover the drug, and FDA will list them publicly in what is known as the Orange Book. *Id.* An

applicant must submit one of several certifications with respect to the Orange-Book-listed patents relevant to its ANDA. *See id.* One is a Paragraph IV certification, which asserts that the patent is invalid, unenforceable, or not infringed. *Id.* at 1118. Filing an ANDA containing a Paragraph IV certification is patent infringement under § 271(e)(2), allowing the brand to sue through a "highly artificial act of infringement." *Eli Lilly & Co. v. Medtronic Inc.*, 496 U.S. 661, 678 (1990); *Celgene*, 17 F.4th at 1118.

Under the Act, section 271(e)(2) is a "highly artificial act of infringement" created "for a very limited and technical purpose"—namely, to resolve patent disputes during a period in which "use of [the] patented invention [is] only for the purpose of obtaining premarketing approval." *Eli Lilly*, 496 U.S. at 678. However, it is only "*[p]rior to FDA approval*, [that] ANDA applicants generally must amend or supplement ANDAs to submit an appropriate patent certification for patents that issue after submission of the ANDA." *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1127–28 (Fed. Cir. 2018) (emphasis added). The remedies specific to the Hatch-Waxman Act under section 271(e)(4) are available only to those actions that are properly brought under section 271(e)(2)(A). *See* 35 U.S.C. § 271(e)(4) ("For an act of infringement *described in paragraph (2)*." (emphasis added)).

C. MYLAN'S ANDA PRODUCTS

AstraZeneca holds the approved New Drug Application ("NDA") for Symbicort®. On June 26, 2018, Mylan submitted ANDA No. 211699 to the FDA, seeking approval to market inhalation aerosol products with budesonide and formoterol fumarate dihydrate in two strengths (160/4.5 µg and 80/4.5 µg) ("Mylan's ANDA"). Mylan's ANDA products are generic versions of AstraZeneca's Symbicort® pMDI products. After nearly 10 years of research and development, and millions of dollars spent in developing its safe and cost-effective generic Symbicort products, the FDA granted final approval to Mylan's ANDA on March 15, 2022. Compl. ¶25.

D. PROCEDURAL BACKGROUND

The present patent infringement suit represents AstraZeneca's third attempt to keep Mylan's ANDA products off the market.

On August 30, 2018, Mylan sent a Paragraph IV letter to AstraZeneca pursuant to 21 U.S.C. § 355(j)(2)(B), notifying AstraZeneca that it had submitted with its ANDA a Paragraph IV certification to the only patents then-listed in FDA's Orange Book, U.S. Patent Nos. 7,759,328 ("'328 patent"), 8,143,239 ("'239 patent"), and 8,575,137 ("'137 patent"). Compl. ¶¶26, 27. AstraZeneca filed suit in October 2018[2], for infringement of the '328, '239 and '137 patents. Case No. 18-cv-193, ECF No. 1. Like the '558 patent, each of the '328, '239 and '137 patents expire on January 29, 2023.

On October 11, 2019, Mylan amended its ANDA to include a Paragraph IV certification to a fourth patent, U.S. Patent No. 10,166,247 ("'247 patent") from the same family as the '328, '239 and '137 patents, listed in the Orange Book for Symbicort®. Compl. ¶27. AstraZeneca amended its Complaint to include allegations that Mylan's ANDA infringed the '247 patent under 35 U.S.C. § 271(e)(2)(A). Case No. 18-cv-193, ECF No. 89. The '247 patent also expires on January 29, 2023.

The parties disputed the meaning of the claim term "0.001%" PVP. *See* Case No. 18-cv-193, ECF No. 317 (Aug. 12, 2020 Mem. Opinion and Order Adopting AstraZeneca's Proposed Construction of the Term "0.001%"). Mylan spent significant time and resources developing its ANDA products that designed around the '328, '239 and '137 patents. However, in order to craft

[2] AstraZeneca filed suits in both the District of Delaware and the Northern District of West Virginia. *AstraZeneca AB V. Mylan Pharms. Inc.*, No. 18-cv-193 (N.D.W. Va.) (hereinafter "Case No. 18-cv-193"). The Delaware case was later transferred to the Northern District of West Virginia and consolidated with the earlier filed case. Before trial, Kindeva Drug Delivery L.P. was substituted for original co-defendant 3M Corp. Case No. 18-cv-193, ECF No. 386.

an infringement argument, AstraZeneca urged that "0.001%" should be construed to cover all PVP concentrations from 0.0005% to 0.0014%, while Mylan construed it in the context of the patent to mean that precise number with only minor variations, from 0.00095% to 0.00105%. *See id.* at 12-13. The issue was critical because the PVP concentration in the proposed ANDA products fell within AstraZeneca's construction, but outside of Mylan's. After the district court adopted AstraZeneca's construction (*id.* at 17), Mylan stipulated to infringement under that construction (*see* Case No. 18-cv-193, ECF No. 349 (Stipulation and Order)). At the same time, AstraZeneca agreed to drop its asserted claims of the '247 patent. *Id.* Both parties reserved their rights subject to the outcome of any appeal. *Id.*

The parties proceeded to a first trial in October 2020, regarding whether the asserted claims of the '328, '239, and '137 were obvious under 35 U.S.C. § 103. *See, e.g.*, Case No. 18-cv-193, ECF No. 431 (Mar. 2, 2021 Mem. Opinion and Order) at 3-4 & n.3. After trial, the district court ruled that the asserted claims would not have been obvious over the prior art. Case No. 18-cv-193, ECF No. 431. Mylan appealed both the district court's claim construction of "0.001%" PVP, as well as its non-obviousness decision. *See AstraZeneca AB v. Mylan Pharms. Inc.*, 19 F.4th 1325, 1329 (Fed. Cir. 2021). On appeal, the Court of Appeals for the Federal Circuit upheld the district court's obviousness finding, but reversed its claim construction of "0.001%" PVP, holding that the term should be construed "as that precise number, with only minor variations, i.e., 0.00095% to 0.00104%." *See id.* As a result, the Federal Circuit vacated the parties' infringement stipulation based on the district court's construction, and remanded for further proceedings. *Id.* at 1335.

On remand, AstraZeneca stipulated that Mylan's ANDA Products did not infringe the asserted claims of the '328, '239, '137, and '247 patents reciting "0.001%" PVP (Case No. 18-cv-193, ECF No. 549), and ultimately proceeded to a second trial, this time on the '247 patent, which

has different, and incredibly broader claims. Given the extraordinary breadth of potential formulations within the scope of these claims, and the very limited number of example formulations in the '247 patent's specification, Mylan asserted at trial that the specification failed to describe or enable the full scope of either claim under Section 112. Case No. 18-cv-193, ECF No. 563-12 at 9-15. Mylan also asserted that the term "stable," required by both claims, was indefinite. *Id.* at 3-9. Trial concluded on May 23, 2022, with post-trial briefing and closing arguments to be completed by June 22, 2022. Case No. 18-cv-193, ECF No. 586.

As the weaknesses in its existing patent portfolio became apparent, AstraZeneca raced to eke out more from their pending applications—filing yet another application in March 2020. Plaintiffs' last-ditch effort finally yielded the '558 patent. But it issued on April 26, 2022—more than a month *after* MPI's ANDA received final FDA approval. *See* Compl. ¶¶11, 25. Undeterred, AstraZeneca filed this suit – seeking a third trial on the newly-issued '558 patent and improperly alleging infringement under the Hatch-Waxman Act. Unlike the predecessor patents, Mylan never submitted a Paragraph IV certification or a notice letter for the '558 patent, as Mylan's ANDA had already received final FDA approval before the '558 patent issued.

III. LEGAL STANDARDS

"A motion to dismiss pursuant to Rule 12(b)(6) tests the sufficiency of the claims pled in a complaint." *ACA Fin. Guar. Corp. v. City of Buena Vista*, 917 F.3d 206, 211 (4th Cir. 2019). A complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). And while this Court "must accept the factual allegations in the complaint as true," it "need not accept a complaint's legal conclusions," and so "simply reciting the cause of actions' elements and supporting them by conclusory statements does not meet the required standard." *Sheppard v. Visitors of Va. State Univ.*, 993 F.3d 230, 234 (4th Cir. 2021)

(quoting *ACA*, 917 F.3d at 212). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Conclusory statements and facts "merely consistent with a defendant's liability" do not suffice to carry a complaint over "the line between possibility and plausibility." *Id.* (cleaned up). Mere "[l]abels, conclusions, recitation of a claim's elements, and naked assertions devoid of further factual enhancement will not suffice." *ACA*, 917 F.3d at 211 (citing *Iqbal*, 556 U.S. at 678).

IV. ARGUMENT – COUNT 1 SHOULD BE DISMISSED FOR FAILURE TO STATE A CLAIM UNDER RULE 12(B)(6)

Count 1, which alleges infringement, should be dismissed under Rule 12(b)(6) for failure to state a claim. AstraZeneca alleges that "the submission of ANDA No. 211699" infringed the '558 patent under 35 U.S.C. § 271(e)(2)(A). Compl. ¶55. But that cannot be, as MPI's ANDA was already approved *before* the '558 patent issued, mooting the need to amend its ANDA to include a Paragraph IV certification to the '558 patent, which was not even listed in the Orange Book until May 20, 2022 – three weeks *after* AstraZeneca filed this suit. At no point did MPI submit an ANDA or amendment for a drug "claimed in" the '558 patent. The patent did not exist until Mylan's ANDA had already been approved by the FDA.

Courts have quickly winnowed out such claims before. The District of Delaware, for example, dismissed a § 271(e)(2)(A) claim where the ANDA in question was approved before the patent in suit issued. *Ferring B.V. v. Actavis, Inc.*, No. 15-4222, 2016 WL 3027446 (D.N.J. May 26, 2016). There, the defendant filed its ANDA in July 2010, and the FDA approved it in December 2012. *Id.* at *1. In 2015, that plaintiff obtained issuance of a new patent and assert it. *Id.* at *4. The court dismissed the patentee's § 271(e)(2) claim. *Id*. Like this case, the patentee in *Ferring* alleged that the defendants had filed an ANDA in the past that happened to infringe now. *Id.* The court

correctly rejected that theory, observing that "the artificial act of infringement" is "triggered by the *filing* of an ANDA," and that filing preceded the patent. *Id.* (emphasis added). And it reasoned that "Congress's inclusion of the phrase 'claimed in a patent' in the statute indicates that a § 271(e)(2)(A) claim must be based upon a patent that has already been issued at the time the infringing ANDA is filed." *Id.*

The rationale of *Ferring* is reinforced by *Celgene*, *Vanda*, and *Valeant*. In each, the Federal Circuit emphasized that *submitting* an ANDA or its amendment is what infringes—specific past acts. *Valeant* explained that "[u]nder the plain language of the statute, the only past infringing act is the ANDA submission." *Valeant Pharms. N. Am. LLC v. Mylan Pharms. Inc.*, 978 F.3d 1374, 1381 (Fed. Cir. 2020). *Celgene* reiterated that "it is the submission of the ANDA, and only the submission, that constitutes an act of infringement in this context." 17 F.4th at 1120 (quoting *Valeant*, 978 F.3d at 1381). And *Vanda* stated that "amend[ing] the ANDA by submitting a Paragraph IV certification" as to a later-issued patent was infringement. *Vanda*, 887 F.3d at 1127.

Each of *Celgene*, *Vanda*, and *Valeant* were predicated on the generic having submitted a Paragraph IV certification with the original submission to the ANDA, or as an amendment to the ANDA. *See Celgene*, 17 F.4th at 1119; *Vanda*, 887 F.3d at 1125, 1127; *Valeant*, 978 F.3d at 1376. Indeed, the "highly technical act" of infringement is tied to the Paragraph IV certification, and applications without one do not give rise to a § 271(e)(2)(A) claim. *See, e.g.*, *Eisai Co. v. Mutual Pharm. Co.*, No. 06-3613, 2007 WL 4556958, at *11–12 (D.N.J. Dec. 20, 2007) (dismissing § 271(e)(2) claim because ANDA did not contain Paragraph IV certification) (collecting cases); *Eli Lilly*, 496 U.S. at 678 (characterizing § 271(e)(2) as "infringement that consists of submitting an ANDA . . . containing the fourth type of certification"). Further, *Vanda* explained that an ANDA filer can be subject to a § 271(e)(2)(A) infringement claim "on a patent that issues after

the filing of the ANDA, *but before FDA approval*." 887 F.3d at 1127 (emphasis added). That is because "[p]rior to FDA approval," ANDA applicants must amend ANDAs with new Paragraph IV certifications to new patents. *Id.* at 1127–28. Here, however, the patent issued after FDA approval, and thus there was no Paragraph IV certification—in fact, Plaintiffs did not even list the patent in the Orange Book until weeks after Plaintiffs filed this suit.[3]

When the '558 patent issued, MPI no longer had an application pending with the FDA seeking to obtain final approval. Mylan has not submitted a Paragraph IV certification to the '558 patent and its already-approved application was never amended when the patent issued. Accordingly, there is no subject matter jurisdiction over this claim and the facts alleged in Plaintiffs' Complaint cannot support a claim for infringement under § 271(e)(2).

Plaintiffs' desire to use the Hatch-Waxman Act as a shield to its lucrative Symbicort monopoly against the very purpose of the Act, which was to get "generic drugs into the hands of patients – fast" should be rebuffed and Count 1 and its accompanying requested relief in paragraphs A, and C-F should be dismissed for failure to state a claim. *In re Barr Lab'ys, Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) ("Congress sought to get generic drugs into the hands of patients at reasonable prices—fast.").

V. CONCLUSION

For the reasons above, Defendants respectfully request that the Court dismiss Count 1 and Prayer for Relief paragraphs A and C-F under Rule 12(b)(6) for failure to state a claim.

[3] Nor could a plaintiff allege infringement under § 271(e)(2)(A) for a hypothetical ANDA amendment that has not yet occurred. *See AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1380–81 (Fed. Cir. 2012).

Respectfully submitted this 1st day of June, 2022.

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CERTIFICATE OF SERVICE

I hereby certify that on the 1ST day of June, I electronically filed the foregoing "**Memorandum of Law in Support of Defendants' Motion to Dismiss**" with the Clerk using the Court's CM/ECF system, which will send notification of the filing to all counsel of record.

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